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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,660

01/10/2005

Hiromu Habashita

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EXAMINER

MURRAY, JEFFREY H

ART UNIT

PAPER NUMBER

1624

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/520,660	<b>Applicant(s)</b> HABASHITA ET AL.	
	<b>Examiner</b> JEFFREY H. MURRAY	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,7-13,20,21,25-29,32-44 and 46-49 is/are pending in the application.
- 4a) Of the above claim(s) 34 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7-13,20,21,25-29,32,33,35-43 and 46-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1, 2, 4-33, 35-43 and 46-49 were rejected in the previous action.
2. Claims 1, 7-13, 20, 21, 25-29, 32, 33, 35-43 and 46-49 are pending in this application. Claims 34 and 44 have been withdrawn. Claims 2-6, 14-19, 22-24, 30, 31, and 45 have been cancelled. This action is in response to the applicants' amendment after a non-final and reply filed on June 5, 2008.

### ***Withdrawn Rejections/Objections:***

3. Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

### ***Claim Objections***

4. Applicant is advised that should claim 35 be found allowable, claims 36-43 and 47-49 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). See the 112, 2<sup>nd</sup> paragraph rejection for more details.

### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

5. Claims 1, 7-13, 20, 21, 25-29, 32, 33, 35-43 and 46-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 2,3-disubstituted pyrazine rings, where the 2-position is attached to an oxygen and

optionally a linker of atoms with a ring, and the 3-position is attached to an aminosulfonyl group attached directly to an optionally substituted thienyl or phenyl group, does not reasonably provide enablement for all other compounds not previously mentioned. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

6. Applicants have traversed this argument and request withdrawal of the rejection. Applicants submit that the specification "meticulously sets forth various processes of manufacturing every possible subgenus of Formula (I)." Applicants go on to cite locations wherein J is bound to ring D via an oxygen and also where G is bound to ring D via an  $\text{-NHSO}_2\text{-}$  group. This, however, is what examiner has stated earlier. Examiner has stated that applicants are entitled to ring D which is a pyrazine ring with an oxygen linker attached in the 2-position and a sulfonamide linker at the 3-position.

Applicants state that the specification "meticulously sets forth various processes of manufacturing every possible subgenus of Formula (I)." Examiner respectfully disagrees. At present, claim 1 allows the "A" ring to be any possible cyclic group, including any and all aryl, heteroaryl, heterocyclic, or carbocyclic rings, or any fused ring systems of the aforementioned combinations. Likewise Ring "B" ring may also be any possible cyclic group, including any and all aryl, heteroaryl, heterocyclic, or carbocyclic rings, with its only real limitation being that it cannot be a multiple ring system. The examiner can envision ring systems numbering in the hundreds which would fit the description laid forth here for either of Ring "A" or Ring "B". Yet the applicants have

shown only two different examples for Ring "A," where ring "A" represents either a phenyl ring or a thienyl ring. The applicants are not enabled for the scope of the claims as they are presently written. The arguments have not been found persuasive and the rejection is hereby maintained.

MPEP §2164.01 (a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the aforementioned factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here that Applicant is not enabled for making these compounds or compositions.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

7. Claims 36-43 and 46-49 still rejected under 35 U.S.C. 112,second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of an intended use, chemical activity, or functional description of some "additional" property for a compound (or moiety/functionality attached to a chemical core) or a composition containing same in a dependent claim, must result in a tangible structural difference between the product and of the independent claim and the product set forth in the dependent claim. In the absence of said structural difference between the product of the independent claim and that of the dependent claim, said dependent claim is seen to be a substantial duplicate, and said recitation is not afforded

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critical weight and fails to further limit the product in said dependent claim. In the instant set of claims, claims 36-43 and 46-49 fail to further limit the claims to compositions from which they depend. They merely state an inherent property of the composition, that of a type of receptor antagonist. This part of the claim is given no patentable weight as it merely describes an "intended use" or a "functional description." The applicants' arguments are not found persuasive. The rejection is hereby maintained.

8. In addition, in the absence of the specific moieties intended to effect modification by "substitution" or attachment to the chemical core claimed, the term "substituted" renders the claim in which it appears indefinite in all occurrences wherein applicant fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicant regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed.

### ***Double Patenting***

9. The double patenting rejection from the previous action is being held in abeyance until allowable subject matter has been indicated. The rejection is hereby maintained for the reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

10. Claims 1, 7-13, 20, 21, 25-29, 32, 33, 35-43 and 46-49 are rejected.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is 571-272-9023. The examiner can normally be reached on Mon.-Thurs. 7:30-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey H Murray/  
Patent Examiner  
Art Unit 1624

**/James O. Wilson/  
Supervisory Patent Examiner, Art Unit 1624**